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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0278 (Prior Notice)

Dear Sir or Madam:

Hansen-Mueller Company welcomes this opportunity to provide comments to the U.S. Food and Drug Administration ("FDA") regarding its proposed rule to implement the provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act" or "Act") requiring prior notice of imported foods. A large importer of various grain products, Hansen-Mueller brings oats and other bulk agricultural products into the United States principally to meet demand that is not met by U.S. production. We are a privately owned, U.S. company operating in the grain merchandising, elevator and milling business for 24 years. The primary responsibility of Hansen-Mueller is to handle, process and transport grain and feed products from suppliers to consumers. As an importer of grains for consumption in the U.S., it is our understanding that Hansen-Mueller would be required to submit prior notice of imports under the proposal.

Among other requirements, the prior notice provision of the Bioterrorism Act requires that FDA issue regulations mandating the submission of notice in advance of any importation of food into the U.S. for the purpose of enabling the article to be inspected at ports of entry. Hansen-Mueller recognizes that the agency's task in implementing this provision is a complex one that is further complicated by the record speed in which the prior notice system must be completed in light of the Act's hammer provision deadline of December 12, 2003. To ensure that FDA implements the Act in an efficient and effective fashion, Hansen-Mueller believes that the agency should make several changes to the proposal in order to minimize disruptions to trade and the overall food supply, while improving the quantity and quality of imported foods inspections.

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Along those lines, Hansen-Mueller urges FDA to enter into agreement with the Department of Homeland Security ("DHS") and/or the U.S. Department of Agriculture's ("USDA") Animal and Plant Health Inspection Service ("APHIS") to allow relevant port inspectors employed by those agencies to inspect and examine bulk grains on behalf of FDA, as expressly contemplated in the Act. Hansen-Mueller also requests the agency to provide much needed clarification as to when FDA would consider a shipment of food to have "arrived" at the port of entry. Additionally, this comment encourages FDA to: alter the deadline for prior notice submission; provide twenty-four staffing; clarify when grower information must be provided in a prior notice submission; allow exporters to submit prior notice; and utilize existing information collection systems in implementing a prior notice system. Hansen-Mueller separately submitted comments to the Office of Management and Budget, a copy of which is attached for your reference.

I. FDA Should Utilize Existing DHS/APHIS Infrastructure In Inspecting Bulk Grains

APHIS inspectors, now under or soon to be transferred to DHS, inspect all shipments of bulk grains Hansen-Mueller and others import into the U.S. It is Hansen-Mueller's understanding that these inspectors are stationed permanently at every major port of entry to perform this duty. FDA inspectors, on the other hand, only intermittently inspect bulk grain shipments and are not stationed permanently at ports of entry for this specific task. It is a highly inefficient use of FDA's scarce resources to require its inspectors to leave their main place of business to perform periodic inspections and tests of grain that is already being tested by APHIS personnel, albeit for different substances (e.g., noxious weed seeds versus microbial contamination).

To eliminate this inefficiency and, thereby, reduce the burden of redundant inspections on bulk grains, Hansen-Mueller strongly urges FDA to utilize the authority provided the agency by Section 314 of the Bioterrorism Act to enter into a memorandum of understanding with DHS and/or USDA to allow APHIS inspectors to conduct inspections and further examinations of bulk grain imports and other food imports on behalf of FDA. This would increase significantly the efficiency of FDA-related bulk grain inspections and examinations at ports of entry, while reducing the burden of bulk grain inspections on both FDA and industry.

II. FDA Should Provide Clarification As To When An Article Of Food Will Be Deemed To Have Arrived At The Port Of Entry

Hansen-Mueller requests FDA to clarify at what point the agency would consider that food imported or offered for import has "arrived" at the port of entry for

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purposes of prior notice. Hansen-Mueller understands that the agency's proposal would require a prior notice submission to include, among other things, the estimated time at which an article of food is expected to arrive at the port of entry (i.e., the port where food first arrives in the U.S.). Although FDA elaborates in the proposal that the port of entry would be "the location where the food first physically appeared in the United States," in the context of ships carrying bulk grain to coastal ports of entry it remains unclear at which point the agency would determine that the bulk commodities had officially arrived. Clarification on this point is necessary to ensure that importers submit accurate and timely arrival times to FDA based on the correct understanding of the time at which the food would be deemed to have arrived in the U.S.

If FDA were to take the position that an article of food has not arrived at the port of entry until the carrier has docked, more flexibility would be needed in the filing of updates to arrival time. FDA proposes to require updates to the anticipated arrival time and port of entry two hours prior to the food's arrival if the carrier will be more than one hour earlier or three hours later than anticipated. Given the logistics and unpredictability of ocean transport, it is not possible to accurately predict arrival time of a carrier within the four-hour window provided. For instance, ocean carriers may have to wait for numerous hours outside of the harbor or at a point of rest within the harbor prior to docking and unloading due to weather delays, vessel traffic, space limitations at the dock, and for countless other reasons. It is likely, therefore, that FDA would have to process thousands of updates each day.

To address this issue, Hansen-Mueller suggests revising the proposed requirements applicable to updates to expand the window of time during which carriers could arrive at the port of entry without having to submit an update to their anticipated arrival time. For example, the agency could require importers to notify FDA at least two hours before the carrier reaches the border if it might arrive more than one hour earlier than anticipated or eight hours later. This approach would provide importers with the flexibility necessary to account for unpredictable delays, while decreasing the paperwork burden on both FDA and industry and maintaining the same level of security at our nation's borders.

III. FDA Should Adopt A Shorter, Rolling Minimum Prior Notice Deadline

Hansen-Mueller encourages the agency to adopt shorter minimum prior notice deadlines based on the mode of transportation, rather than the proposed fixed time of noon the calendar day before arrival. Shorter prior notice periods that are not fixed to a certain time of day, but rather tied to the arrival time of the individual shipment of food due to arrive at the port of entry, would avoid the inevitable bombardment of prior notice

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submissions FDA would receive at noon every day under the proposal. This would allow the agency to allocate its resources more efficiently. Additionally, a shorter prior notice period would allow importers and shippers to provide a better estimate of arrival time such that fewer updates and cancellations of prior notice submissions would have to be submitted to the agency, again saving both FDA and industry resources.

Hansen-Mueller believes that a minimum notice period of eight hours for coastal ports of entry would be viable from the point of view of brokers and importers and give FDA a substantial period of time to determine whether sampling/inspection of any particular shipment is warranted. FDA may consider imposing an even shorter minimum notification period, perhaps two hours, for products arriving by truck or rail from Canada or Mexico. Providing for entry of additional pertinent information into the OASIS or prior notice system (e.g., Customs-Trade Partnership Against Terrorism ("CTPAT") participation, low risk importer status) would further enhance the meaningfulness of FDA's sampling/inspection selections.

IV. FDA Should Provide Twenty-Four Hour Staffing

In order to effectively implement the prior notice requirement, FDA must make its inspection staff available 24 hours a day, seven days a week. If the agency were to otherwise limit its availability for inspections, shipments arriving after business hours would have to be placed on hold for several hours or days while waiting for inspectors to return to their posts. Because food arrives at ports of entry at all hours of the day and night, even on the weekends, this would literally paralyze the flow of commerce into the United States.

V. FDA Should Clarify When Grower Information Must Be Included In Prior Notice Submissions

The Act requires prior notice submissions to include grower information, if known. The flexibility reflected by this requirement is of great importance. Bulk grain is typically imported via large ocean carriers that contain many tons of grain grown by hundreds of different growers. It would be cost-prohibitive, in terms of time and money, to determine every one of those growers. Therefore, Hansen-Mueller supports and emphasizes the "if known" qualification and encourages FDA to clarify that when grower information is not readily accessible to the importer, or impracticable to obtain, such information would not be required.

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VI. FDA Should Allow Exporters to Submit Prior Notice

Hansen-Mueller encourages FDA to allow foreign companies that do not reside or maintain a place of business in the United States to submit prior notice of food imports. The agency proposes to allow only a limited group of entities to submit prior notice: a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or U.S. importer (e.g., an import broker). FDA states in the preamble that it chose these U.S. entities because, among other reasons:

> [the agency believes] that it is the U.S. importer or U.S. purchaser who orders or buys the article of food, thereby initiating its importation into the United States. These persons thus should possess, or have the ability to obtain, the information required to be submitted in the prior notice within the time period in proposed Sec. 1.286.

The agency further concludes that restricting the persons who can submit prior notice to the U.S. entities described above would "minimize confusion about who should or will submit prior notice among the several parties who can be involved in importing food."

Hansen-Mueller disagrees with the agency's conclusion and believes that restrictions on who can submit prior notice would actually complicate matters. The Bioterrorism Act does not in anyway place limitations on who can submit prior notice. This decision is one for the parties involved in the transaction to make, not for the government. In many instances, the foreign shipper or exporter acts as the importer of record for Customs' purposes and, thus, submits the necessary paperwork for satisfying Customs' requirements. In this situation, the exporter would be the most appropriate entity to submit prior notice to FDA. To require exporters to relay the prior notice information, particularly with respect to updates, through a third party is simply not necessary and would create more confusion overall.

VII. FDA Should Utilize Existing Information Collection Systems

Hansen-Mueller strongly urges FDA to utilize existing information collection systems in implementing the prior notice requirement. Hansen-Mueller understands that the agency is in the process of developing a new information collection system for prior notice submissions that would be independent of and separate from existing FDA and U.S. Customs Service ("Customs") systems. Implementation of an entirely new system would, however, require importers to submit to FDA essentially the same information twice: 1) to

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the prior notice system currently under development; and 2) to Customs' Automated Broker Interface ("ABI"), which routes the information to FDA's OASIS system for an inspection determination. FDA would, in turn, have to make two separate decisions as to the admissibility of the food. Utilizing existing systems would eliminate this redundancy. Moreover, it would save FDA the majority of the $4.4 billion earmarked toward the creation and implementation of a new prior notice system.

Hansen-Mueller appreciates that implementing the prior notice requirement through existing FDA/Customs information systems will present practical difficulties. The bulk of the necessary infrastructure is already in place, however. Along those lines, Hansen-Mueller understands that Customs' Automated Commercial System ("ACS") already permits brokers to enter OASIS data via the ABI interface prior to actual importation of a shipment, although data is not currently transmitted to FDA until entry is actually made.

Hansen-Mueller recognizes that FDA and Customs determined that the ABI/OASIS interface could not be modified to meet the data requirements of the proposed prior notice regulation by the December 12, 2003 statutory deadline. The proposal would require, however, the submission of far more information than Congress directed FDA to collect with respect to prior notice submissions. It does not appear that FDA and Customs considered whether the existing information systems could be modified to accommodate only the limited information required by the Act, rather than the additional data FDA proposes to collect. Hansen-Mueller, therefore, urges the agencies to assess whether the systems could accommodate the rather minor modifications described below that should be necessary to collect the information required by the Act alone.

To act also as a prior notice system, the ABI/OASIS interface would have to be modified in two critical ways. First, all OASIS data submitted by brokers in the ABI system prior to importation would have to be immediately transmitted to FDA. Second, a broker that enters OASIS data prior to importation would have to receive an immediate acknowledgement of the entry. With these minor changes, the OASIS data entered by the broker can function as advance notice of importation required by the Act. The only information required by the Act that is in addition to the information provided FDA under the OASIS system is the grower identity and anticipated port of entry. Thus, to perfect the combination prior notice/OASIS system, the OASIS data screen in the ABI would have to be modified slightly to allow for entry of information concerning the grower of the article and the anticipated port of entry.

If system constraints preclude combining the prior notice and OASIS systems into one, Hansen-Mueller recommends that FDA, at a minimum, attempt to link the new

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prior notice system to the ABI/OASIS interface such that relevant information in a prior notice submission would be forwarded automatically to the ABI/OASIS interface. As mentioned above, the new prior notice system would receive the same information inputted in the OASIS system, along with additional information required by the proposal. Linking the systems would eliminate the need for importers to enter and submit to FDA the same information twice, as would be required if the two systems remained independent of one another.

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Hansen-Mueller recognizes the important roles industry and government play in enhancing our homeland security. At the same time, in creating new regulatory requirements, it is imperative that FDA not lose sight of sound principles of good government in terms of efficiency and effectiveness.

Thank you for your consideration of our views. We welcome the opportunity to provide any additional information.

Sincerely,

John W. Orr
President

Enclosure